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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/484,048 01/18/00 STEEN

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EXAMINER

SAUCIER, S

ART UNIT	PAPER NUMBER
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1651

DATE MAILED:

02/08/01

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/484,048

Applicant(s)

Steen

Examiner
Sandra Saucier

Group Art Unit
1651



☒ Responsive to communication(s) filed on Jan 25, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-23 is/are pending in the application.

Of the above, claim(s) 2-4 and 8-23 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 5-7 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) 09/093,614

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1, 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Claims 1-23 are pending. Claims 1, 5-7 are considered on the merits. Claims 2-4, 8-23 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 2-4, 8-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 7.

Priority

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Sweden on 12/15/95. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the parent United States application, 09/093614 was filed more than twelve months thereafter.

Please note that the oath/declaration submitted 4/20/2000 has the wrong title of invention, and does not claim priority to PCT/SE96/01664. Also, an amendment has been made to the oath without dating and initialing (See citizenship). A new oath/declaration is suggested if applicant wishes to be entitled to his Swedish application date of priority.

Specification

The disclosure is objected to because of the following informalities: The first paragraph of the specification should claim benefit of 09/093614. Please delete the first sentence of the second paragraph and insert the material after the title.

Appropriate correction is required.

INDEFINITE

Claims 1, 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the solution comprises calcium. Calcium is a metal and is not soluble in such a solution. Perhaps calcium ion is meant.

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Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 92/18136 [AL] or Ingemansson *et al.* [AV].

The claims are directed to a composition comprising calcium(ion), at least one colloid and optionally nitroglycerin.

WO 92/18136 disclose a composition comprising Ca⁺⁺ and dextran, see claim 4.

Ingemansson *et al.* disclose a composition comprising Ca⁺⁺ and dextran, see Table 1.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ingemansson *et al.* [AV] and Pinsky *et al.* [AQ] or Naka *et al.* [AT].

The claims are directed to a composition comprising

Ca⁺⁺,
5% dextran 40KDa,
5mM dextrose,
6mM K⁺
0.8mM Mg⁺⁺
138 mM Na⁺,
142 mM Cl⁻,
0.8mM sulfate anion
0.24mM THAM,
0.8mM phosphate anion,
optionally nitroglycerin.

The references are relied upon as explained below.

Ingemansson *et al.* disclose a commercial composition, Perfadex plus Ca⁺⁺, used to preserve vasculature comprising
1.5mM Ca⁺⁺,
5% dextran 40,
5mM dextrose,
6mM K⁺,
0.8 mM Mg⁺⁺
138 mM Na⁺,
142 mM Cl⁻,
0.24mM THAM
0.8mM phosphate anion

This composition is lacking the inclusion of nitroglycerin.

Pinsky *et al* or Naka *et al.* disclose that nitroglycerin maintains vascular homeostasis. It is added to known perfusion and preservative solutions such as lactated Ringer's in an amount of 0.01-0.1 mg/ml = 5-50µM.

The addition of nitroglycerin to the solution of Ingemansson *et al.* would have been obvious when taken with Pinsky *et al.* or Naka *et al.* which teach the

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addition of nitroglycerin to maintain vascular homeostasis to preservative solutions.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ingemansson *et al.* [AT] and Nozick *et al.* [AU] Pinsky *et al.* [AQ] or Naka *et al.* [AT].

Ingemansson *et al.* disclose a commercial composition, Perfadex, used to preserve vasculature comprising:

5% dextran 40,
5mM dextrose,
6mM K⁺,
0.8 mM Mg⁺⁺
138 mM Na⁺,
142 mM Cl⁻,
0.24mM THAM
0.8mM phosphate anion

This composition is lacking the inclusion of Ca⁺⁺ and nitroglycerin.

Nozick *et al.* disclose that solutions used to irrigate vascular grafts should contain Ca⁺⁺ in order to avoid damage to the graft.

The inclusion of Ca⁺⁺ to the solution disclosed by Ingemansson would have been obvious when taken with Nozick *et al.* who teach that the presence of calcium ion in solutions is critical to the maintaining of vascular grafts prior to transplantation.

Pinsky *et al.* or Naka *et al.* disclose that nitroglycerin maintains vascular homeostasis. It is added to known perfusion and preservative solutions such as lactated Ringer's or University of Wisconsin Solution in an amount of 0.01 - 0.1 mg/ml = 5-50µM (see abstract).

One of skill in the art would have been motivated at the time of invention to make these additions in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art

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as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claim Objections

Claims 5 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 5 and 7 appear to be directed towards allowable subject matter. Please redraft them in independent form and add further limitations to the composition if desired and methods of use claims limited to the allowable composition if desired. Upon cancellation of the rejected claims, these new claims will be allowed upon presentation.

Declaration

The inventor's declaration has been carefully considered.

It appears that the inventor argues that preservation solutions and "extracellular" solutions are distinct because preservation solutions are created for cold organ storage, while extracellular solutions may be used to irrigate and rinse tissues. While this distinction may be appreciated particularly with regard to method of use claims, the instant claims are directed to a composition which has Perfadex as a base. Perfadex is a solution which has been used in the prior art also to "flush organs" (Ingemansson et al., page 1210). Thus, to add components which have been shown in the prior art to be valuable while rinsing or flushing organs to a composition which has been used to rinse or flush organs is obvious. Please note that a composition may be used for many purposes and the examiner does not need to have the same motivation as the inventor to combine components (references), merely a motivation which may be reasonable given any disclosure in the references.

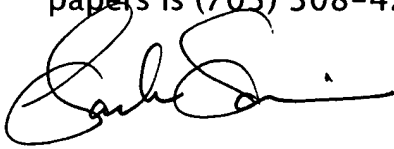
The inventor further argues that nitroglycerin is not advocated to be added to preservation solutions, only to extracellular solutions such as Ringer's. Please note that Pinsky *et al.* also adds nitroglycerin to University of Wisconsin solution (abstract), which the inventor has stated in the declaration is a preservation solution. Thus, the inventor's arguments are unpersuasive with regard to this point.

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The inventor's arguments are concerning structural effects and functional effects may be correct and be of great academic interest; however, the method of function of a component, particularly when examining composition claims, is of little patentable weight.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Service Desk at (703) 308-0196. The number of the Fax Center for the faxing of papers is (703) 308-4227.



Sandra Saucier
Primary Examiner
Art Unit 1651
February 5, 2001